

## 510(k) Summary of Safety and Effectiveness

### Submitter

Shenzhen Creative Industry Co., Ltd.  
2/F, Block 3, Nanyou Tian'an Industry Town,  
Shenzhen, GD, 518054 P. R. China 518054  
**Fax:** +86 755 2643 2832  
**Tel.:** +86 755 2643 3514  
**E-mail:** market@creative-sz.com

JAN 10 2008

### Device Name

Trade Name: PC-80 /Prince 180 Easy ECG Monitor  
Common Name: ECG Monitor  
Classification Name: Electrocardiograph (21CFR870.2340)  
Classification: Class II

### Predicate Devices (Legally Marketed Devices)

The predicate device for ECG Monitor, Model PC-80 /Prince 180 Easy ECG Monitor series is:

**Omron Healthcare, Inc.**  
Omron Portable ECG Monitor  
Model: HCG-801  
510(K) number: K060766

### Device Description

PC-80 / Prince 180 Easy ECG Monitor is a handheld electrocardiograph unit which can measure, display, and store ECG data by the user. The device can calculate the average heart rate and display the heart rhythm after analysis. Furthermore, it's small, light, and easy to use. A 30-second ECG record is measured and stored in this device. The waveform data and heart rate value can be displayed on LCD screen, and those ECG data records can be reviewed.

### Intended Use

The device is a handheld, personal electrocardiograph (ECG) unit, which can measure electrical activities of the heart easily and conveniently. It's a single LEAD ECG monitor for home health care use. The users can use it themselves to check their heart condition. The device can detect average Heart Rate, display ECG waveform, and give some information about heart rhythm.

It is suitable for the adult user who suffers from cardio-vascular disease, or adults who care about their heart functions during their daily life.

This device is not intended for use as a conventional diagnostic tool, but use as a healthcare tool which can provide a doctor recorded data as a reference. This device is also not intended for recording and transmission of user's ECG signal simultaneously, and it's not recommended for use with an implanted pacemaker.

The unit is suitable for personal use at home, not suitable for long term monitoring, but spot-checking or clinical patrol at a medical institution or hospital.

## **Summary of Technical Characteristics of the Device Compared to the Predicate Devices (Legally Marketed Devices)**

The Shenzhen Creative Industry PC-80/Prince 180 Easy ECG Monitor and the Omron ECG Model HCG-801 are used to monitor heart rates via three electrodes. The Omron monitors from 2-200 bpm and the Shenzhen device monitors from 30-240 bpm. Both devices use two AAA batteries and are software driven. Both devices are for use on adults and are for prescriptive use. The Shenzhen device's electrodes can be placed on the chest, leg, and palm; however, the Omron device is to be used on the Chest only. They are similar in weight and operating environments.

## **Summary of Performance Testing**

The Shenzhen Creative Industry Co, LTD PC-80/Prince 180 ECG Easy Monitor has undergone IEC 60601-1, IEC 60601-1-2 and AAMI EC 38 testing validation. PC-80/Prince 180 ECG Easy Monitor substantially have been tested in accordance with the system V & V plan and summary included with the submission using production equivalent units prior to release to market.

A risk analysis identifying potential hazards and documenting mitigation of the hazards have been developed and applied as part of Shenzhen Creative Industry Co., LTD design control procedure. Shenzhen Creative Industry Co., LTD quality system confirms to 21CFR820, MDCAS ISO 13485 certified by ORKI.

## **Conclusions**

As stated above, the Shenzhen Creative Industry Co, LTD PC-80/Prince 180 ECG Easy Monitor is safe and effective, complies with the appropriate medical device standards, and is substantially equivalent to the earlier identified predicate device.

- End of Section -



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 10 2008

Shenzhen Creative Industry Co., Ltd.  
c/o Mr. Mark Job  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
Buffalo, MN 53313

Re: K073152

Trade/Device Name: Easy ECG Monitor Models PC-80 and Prince 180

Regulation Number: 21 CFR 870.2800

Regulation Name: Medical magnetic tape recorder

Regulatory Class: Class II (two)

Product Code: DSH

Dated: December 18, 2007

Received: December 19, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 -Mr. Mark Job

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if know):

Device Name: Easy ECG Monitor

Model Name 1: PC-80

Model Name 2: Prince 180

Shenzhen Creative Industry Co., Ltd.

Indications for Use:

The device is a handheld, personal electrocardiograph (ECG) unit, which can measure electrical activities of the heart easily and conveniently. It's a single LEAD ECG measuring device for home health care use, which can detect, display and store ECG signal, and if possible, provide average heart rate message after ECG measurement. The users can use it themselves to check their heart condition.

It is suitable for the adult users (age 18 or older), who suffers from cardio-vascular diseases, or the adult people who are caring about their heart working conditions during their daily life. This device is not intended for use as a conventional diagnostic tool, but use as a healthcare tool which can provide doctor the recorded data as references. This Device is also not intended for recording and transmission of user's ECG signal simultaneously, and it's not recommended to use with implanted pacemaker.

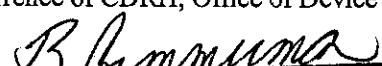
Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K073152